

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

<b>Trade name or designation of the mixture</b>	OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control, Sure-Vue Signature Mono Test Negative Control
<b>Registration number</b>	-
<b>Synonyms</b>	Mono CONTROL -
<b>Kit number</b>	145, 755725, 23-200-275
<b>Issue date</b>	22-May-2012
<b>Version number</b>	01
<b>Revision date</b>	-
<b>Supersedes date</b>	-

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

<b>Identified uses</b>	Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For use in the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis. For In Vitro Diagnostic Use Only.
<b>Uses advised against</b>	Use in accordance with supplier's recommendations.

### 1.3. Details of the supplier of the safety data sheet

<b>Corporate Headquarters</b>	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042
<b>Distributor</b>	Sekisui Diagnostics (UK) Limited 50 Gibson Drive, Kings Hill, West Malling Kent ME19 4AF UK www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022 info@sekisuidiagnostics.com
<b>Contact person</b>	Americas 1-760-476-3962

### 1.4. Emergency telephone number

Europe, Middle East & Africa +1-760-476-3961  
Asia Pacific +1-760-476-3960  
333512

### Access code

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

**Classification** Xn;R22

The full text for all R-phrases is displayed in section 16.

#### Classification according to Regulation (EC) No 1272/2008 as amended

#### Hazard summary

<b>Physical hazards</b>	Not classified for physical hazards.
<b>Health hazards</b>	Harmful if swallowed.
<b>Environmental hazards</b>	Not classified for hazards to the environment.
<b>Specific hazards</b>	Avoid contact with eyes and skin. Do not ingest or inhale.
<b>Main symptoms</b>	Ingestion may cause irritation and malaise.

### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

<b>Hazard pictograms</b>	None.
<b>Signal word</b>	None.
<b>Hazard statements</b>	The mixture does not meet the criteria for classification.

## Precautionary statements

<b>Prevention</b>	None.
<b>Response</b>	None.
<b>Storage</b>	None.
<b>Disposal</b>	None.

**Supplemental label information** None.

**2.3. Other hazards** Not assigned.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium azide	0.2	26628-22-8 247-852-1	-	011-004-00-7	#
<b>Classification:</b>	<b>DSD:</b>	T+;R28, R32, N;R50/53			
	<b>CLP:</b>	Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410			

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments** The full text for all R- and H-phrases is displayed in section 16. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## SECTION 4: First aid measures

**General information** Not available.

### 4.1. Description of first aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Ingestion</b>	If material is ingested, immediately contact a physician or poison control centre.

**4.2. Most important symptoms and effects, both acute and delayed** Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

**4.3. Indication of any immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** The product is not flammable.

### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
<b>Unsuitable extinguishing media</b>	None known.

**5.2. Special hazards arising from the substance or mixture** When heated to decomposition, may produce hydrazoic acid fumes.

### 5.3. Advice for firefighters

<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**For emergency responders** Use personal protection as recommended in section 8 of the SDS.

- 6.2. Environmental precautions** Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.
- 6.3. Methods and material for containment and cleaning up** Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
- 6.4. Reference to other sections** For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

- 7.1. Precautions for safe handling** Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
- 7.2. Conditions for safe storage, including any incompatibilities** Store at controlled room temperature at 15–30 °C (59–86°F). Store in a closed container away from incompatible materials.
- 7.3. Specific end use(s)** For in vitro diagnostic use.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m <sup>3</sup>
	TWA	0.1 mg/m <sup>3</sup>

##### EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m <sup>3</sup>
	TWA	0.1 mg/m <sup>3</sup>

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived no-effect level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

### 8.2. Exposure controls

**Appropriate engineering controls** Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

#### Individual protection measures, such as personal protective equipment

**General information** Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection** Wear approved safety glasses or goggles.

#### Skin protection

**- Hand protection** Wear appropriate chemical resistant gloves.

**- Other** Wear lab coat or other protective garments. Remove contaminated clothing promptly.

**Respiratory protection** Under normal conditions, respirator is not normally required.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** Handle in accordance with good industrial hygiene and safety practices.

**Environmental exposure controls** Inform appropriate managerial or supervisory personnel of all environmental releases.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Appearance** Clear. Colourless liquid.

**Physical state** Liquid.

**Form** Liquid.

**Colour** Colourless, clear.

**Odour** Not available.

<b>Odour threshold</b>	Not available.
<b>pH</b>	7 approximately
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not applicable.
<b>Vapour density</b>	Not applicable.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not applicable.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	Stable at normal conditions.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	Not available.
<b>10.4. Conditions to avoid</b>	Protect against direct sunlight.
<b>10.5. Incompatible materials</b>	Strong oxidising agents. Acids. Heavy metals.
<b>10.6. Hazardous decomposition products</b>	None.

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

### Information on likely routes of exposure

<b>Ingestion</b>	May be harmful if swallowed.
<b>Inhalation</b>	Vapours may irritate throat and respiratory system and cause coughing.
<b>Skin contact</b>	Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
<b>Eye contact</b>	Splashes in the eyes may cause redness and irritation.

**Symptoms** May cause eye irritation on direct contact.

### 11.1. Information on toxicological effects

**Acute toxicity** May be harmful if swallowed.

Components	Species	Test results
Sodium azide (CAS 26628-22-8)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg

**Skin corrosion/irritation** Prolonged skin contact may cause redness, irritation and dry skin.

**Serious eye damage/irritation** Not classified.

**Respiratory sensitisation** Not classified.

<b>Skin sensitisation</b>	Not classified.
<b>Germ cell mutagenicity</b>	Not classified.
<b>Carcinogenicity</b>	Not classified.
<b>Reproductive toxicity</b>	Not classified.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not classified.
<b>Mixture versus substance information</b>	Not available.
<b>Other information</b>	Not available.

## SECTION 12: Ecological information

**12.1. Toxicity** No data available.

Components	Species	Test results
Sodium azide (CAS 26628-22-8)		
<b>Aquatic</b>		
Crustacea	EC50	Water flea ( <i>Daphnia pulex</i> ) 2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill ( <i>Lepomis macrochirus</i> ) 0.68 mg/l, 96 hours

**12.2. Persistence and degradability** No data is available on the degradability of this product.

**12.3. Bioaccumulative potential** Not available.

**Partition coefficient n-octanol/water (log Kow)** Not available.

**Bioconcentration factor (BCF)** Not available.

**12.4. Mobility in soil** Not available.

**Mobility in general** The product is soluble in water.

**12.5. Results of PBT and vPvB assessment** Not a PBT or vPvB substance or mixture.

**12.6. Other adverse effects** Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Residual waste** Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

**EU waste code** Waste codes should be assigned by the user based on the application for which the product was used.

**Disposal methods/information** Dispose in accordance with all applicable regulations. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

## SECTION 14: Transport information

### ADR

The product is not covered by international regulation on the transport of dangerous goods.

### RID

The product is not covered by international regulation on the transport of dangerous goods.

### ADN

The product is not covered by international regulation on the transport of dangerous goods.

### IATA

The product is not covered by international regulation on the transport of dangerous goods.

### IMDG

The product is not covered by international regulation on the transport of dangerous goods.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**

Not listed.

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**

Not listed.

#### Authorisations

**Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation**

Not listed.

#### Restrictions on use

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**

Not regulated.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not regulated.

#### Other EU regulations

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not regulated.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Sodium azide (CAS 26628-22-8)

**Directive 94/33/EC on the protection of young people at work**

Sodium azide (CAS 26628-22-8)

#### Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Additional information is given in the Safety Data Sheet.

#### National regulations

The product has been classified according to the legislation in force.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

#### List of abbreviations

DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.  
PBT: Persistent, bioaccumulative and toxic.  
vPvB: Very Persistent and very Bioaccumulative.

#### References

Not available.

#### Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

#### Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.  
R28 Very toxic if swallowed.  
R32 Contact with acids liberates very toxic gas.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H300 - Fatal if swallowed.  
H400 - Very toxic to aquatic life.  
H410 - Very toxic to aquatic life with long lasting effects.

#### **Training information**

Not available.

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